REMARKS

I. INTRODUCTION

This Amendment and Response is a full and timely response to the Office Action mailed July 27, 2007. Upon entry of this amendment, claims 1-32 remain pending in this application. The Office Action rejected claims 1-6, 8-15, 17-20, and 22-32 under 35 U.S.C. § 103(a). Claims 7, 16, and 21 were also rejected under § 103(a) in view of an additional reference. Claims 1, 9, 19, 24, 30, 31, and 32 have been amended to further clarify the invention claimed by claims 1, 9, 19, 24, 30, 31, and 32. The rejections are traversed. Applicants respectfully requests consideration and entry of the amendments and allowance of the pending claims.

II. REJECTION OF CLAIMS 1-6, 8-15, 7-20, 22-32 UNDER 35 U.S.C. § 103(a)

The Office Action has rejected claims 1-6, 8-15, 7-20 and 22-32 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,476,438 to Edrich ("*Edrich*") in view of U.S. Patent No. 5,556,372 to Talish ("*Talish*") and further in view of U.S. Patent No. 4,570,487 to *Gruber* ("*Gruber*"). Applicants respectfully traverse the rejection and submit that the claims, as amended, are currently in condition for allowance and request that the rejections be withdrawn.

A. The *Edrich* Reference

As an initial matter, the Office Action, Section 3, pages 2-6, generally recites elements of *Edrich*. Specifically, the Office Action recites the description of Figure 3 from the *Edrich* specification, but provides no reference to the recited claims it asserts are taught by the reference. Should these remarks not be persuasive and the rejection not be withdrawn,

Applicants respectfully request a more definite statement regarding which teachings of *Edrich* are being used against specific recited elements.

The claims recite a method and an apparatus structurally different from that of *Edrich*. *Edrich* is directed to focusing ultrasonic waves on a small area and applying electromagnetic waves orthogonally. The Office Action cites column 2, lines 25-31 of *Edrich*, stating,

> 'the method of the invention achieves the unexpected advantage that by the superimposition of the focused ultrasound, the relatively large magnetic fields required to be effective can be directed onto a single nerve bundle. . .' Superimposition is defined as to lay on top. With respect to the applicant's limitation of modulating the acoustic wave, the superimposition by the ultrasound of the reference means the same thing. The electromagnetic wave is laid onto to[sic] of the ultrasound wave to focus the therapy of the reference is the same thing as the ultrasound wave modulated by the electromagnetic wave.

(page 4.) Respectfully, the Office Action mis-represents the recited claims, which have been further clarified by amendment. The superimposition of *Edrich* is not what is recited by the claims. The use of both ultrasound and magnetic waves, alone, does not result in an enhanced therapy, but the therapy must be properly directed for a particular application, as *Edrich* itself teaches.

The *Edrich* reference, in fact, teaches away from the claimed invention because the structure of the method and apparatus described cannot be separated from its use. *Edrich* teaches an invention to solve the problem of

> magnetic fields [that could not] be focused into a small volume of less than one (1) cubic centimeter, which is important for various reasons. Precise focusing of relatively strong fields . . . into a single nerve bundle or into one central nerve region, such as the motor area of the thumb in the precentral cortex region, is required; otherwise, the adjacent area . . . would also be stimulated unintentionally.

(col. 1, lines 28 – 40). Further,

> [t]he method of the invention for neuromagnetic stimulation provides the steps of applying a magnetic field with a magnetic induction B to the nerve tissue to be stimulated and simultaneously directing a focused beam of ultrasonic waves into the magnetic region such that the ultrasonic waves vibrate orthogonal to the direction of the magnetic field, thereby producing a subcutaneous focus having a focal diameter of approximately 1 cm.

(cols. 1-2, lines 64 – 4). On its face, *Edrich* is limited to magnetic stimulation of nerve tissue in the brain, NOT directed to the treatment of bone or other tissue. The *Edrich* invention was intended to substantially limit the magnetic stimulation to a particular, and very small, region of the brain so as not to harm adjacent regions with similar stimulation. The claimed invention does not require or recite such pinpoint accuracy.

The independent claims, as amended, not only recite the treatment is directed to bone tissue, but that the ultrasonic transducer and electromagnetic coil are positioned to direct ultrasound and "electromagnetic energy toward said treatment area *adjacent to* the bone defect or injury. . . ." (*See*, claim 1.) *Edrich* teaches a therapy using ultrasonic and electromagnetic waves to *limit and focus* the area of the particular therapy to a particular area of nerves in the brain, but the claimed invention is beneficial because of the *propagation and augmentative effects* of both the electromagnetic and ultrasonic waves *towards* a bone injury or defect. (*See*, Specification, page 2, line 19 – page 3, line 22.) The Office Action fails to take notice of the fundamental differences between *Edrich* and the invention recited by the Applicants in the claims – *Edrich* is directed to *limiting* a therapy to a small area, whereas the therapy in the recited claims is beneficial due to its propagation through bone tissue.

B. The Combination of *Edrich* and *Talish*

The Office Action states that the apparatus of *Talish* "can be positioned to administer therapy to any desired region rather than the helmet like structure of Edrich et al. '438, such as adjacent to an injury defect in bone." The Applicants respectfully submit that such a combination is not supported for the very reason that the Office Action provides. The *only* apparatus taught by *Edrich* is a helmet-like or other structure that is *only* meant to be used on the head for neural stimulation. The combination of *Edrich* with *Talish* that may "administer therapy to any desired region" is the improper product of hindsight, and the two inventions are meant to solve completely different problems.

"[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. . . . [C]laimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR Intern. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007). The Office Action has failed to identify a reason why one of ordinary skill in the art would combine the elements of an invention meant solely for use on the head of a person with an invention that allows treatment to be effected on other areas of the body. Applicants respectfully submit that the combination is improper.

C. The Combination of *Edrich* and *Talish* with *Gruber*

The Office Action states that "Edrich et al. in view of Talish et al. do not specifically disclose that the electromagnetic coil is adapted to be selectively positioned in different orientations with respect to the ultrasonic transducer to vary the modulation of the ultrasound energy." The Office Action further states that *Gruber*

> disclose[s] the use of a first and second transducer, with the second transducer having a different angular orientation to the examination surface than said first transducer (column 13, lines 13-25). At the time of the invention, it would have been obvious to one of ordinary skill in the art to selectively position the electromagnetic coil in different orientations with respect to the ultrasonic transducer. The motivation for doing so would be to cross-focus the energies through the target area to enhance the signal-to-background ratio . . . (column 8, lines 37-46).

Applicants respectfully submit that the Office Action has improperly expanded the teachings of *Gruber* to apply the use of two ultrasound transducers to limit background noise in an imaging function to teach varying electromagnetic energy in combination with ultrasound to enhance a therapy. *Gruber* does not satisfy the limitation as recited in claims 1, 9, 19, 24, 30, 31, and 32, and the combination of *Gruber* with *Talish* and *Edrich* is not supported.

Gruber teaches the use of two transducers, not the combination of a transducer and an electromagnetic coil. The transducers of *Gruber* do not both emit ultrasound waves that augment and enhance the effects of each other. While one transducer emits differing wave types (e.g., longitudinal or shear), the second transducer acts as a receiver for any reflected or refracted waves in order to image and analyze a flaw in the structure.

> The SLIC-40 module improves the signal-to-background ration by novel combinations of bimodal transducers to produce through multiple one sided cross focusing enhanced signals, which collectively result in an easily discernible pulse pattern comprised of predictable times of arrival, a constant pulse separation and characteristic relative amplitude patterns.

(col. 5, lines 59-66.) Further,

> [a]ngling the receiving transducer to only receive ultrasonic waves striking the entry surface-module boundary at a selected location and at a selected angle *limits* the received ultrasonic waves to those originating in at[sic] the target area. This *excludes* ultrasonic

> reflections, diffractions, etc. (interference) from regions outside the target area.

(col. 6, lines 21-27; *emphasis* added.) *Gruber* also teaches *away* from the "superimposition" that the Office Action asserts is essential to the application of *Edrich* to the recited claims. (*See* Office Action page 4). The ultrasonic (no electromagnetic) waves and angled transducers of *Gruber* facilitate imaging flaws in the structure via an arrangement that mitigates the interference from propagating, reflecting, or refracting ultrasound waves. The electromagnetic field generated by the coils, as recited in the claims, excites the ions within the bone to facilitate *propagation of* or modulate the ultrasonic waves in order to augment and enhance the treatment. (*See*, Specification, page 2, line 19 – page 3, line 22; emphasis added.) The claims recite varying the positions of the transducer and the electromagnetic coil to modulate the ultrasonic waves – and therefore enhance treatment – with the electromagnetic field, not cancel them out. (Claims 1, 9, 19, 24, 30, 31, and 32.)

As stated above, it is important to identify reason for one of ordinary skill in the art to combine the references. *See KSR Intern. Inc.*, 127 S.Ct. at 1741. The Office Action has identified no such reason here, other than to say that it would have been obvious to combine *Gruber* and *Edrich* to enhance the signal to background ratio. The claimed invention does not enhance the signal to background ratio, but relies on the propagation of the waves, facilitated by the electromagnetic energy, necessarily resulting in refractions and reflections, to enhance therapy. Both *Gruber* and *Edrich* seek to *limit* the propagation of waves to the surrounding environment. Therefore, their combination would not be identified by one of reasonable skill in the art, nor does it result in the elements recited by the claims.

Applicants respectfully request that the Examiner consider the above remarks, submit that the claims, as amended, are in condition for allowance, and request that the rejection be withdrawn.

II. REJECTION OF CLAIMS 7, 16 AND 21 UNDER 35 U.S.C. 103(a)

The Office Action rejected claims 7, 16 and 21 under 35 U.S.C. § 103(a) as being unpatentable over *Edrich* in view of *Talish* in further view of U.S. Patent No. 6,050,943 to Slayton ("*Slayton*"). Applicants respectfully traverse the rejection and respectfully refer the Examiner to Parts II.A. and II.B., above, for its discussion of the inapplicability of the *Edrich* reference and its combination with *Talish.*

Claims 7, 16, and 21 were rejected in further view of *Slayton* because, as the Office Action states, "Slayton[] teaches a single ultrasound transducer that can both image and treat tissue." Claims 7, 16, and 21 recite "receiving diagnostic data", which is the diagnostic data defined as image and tissue analysis data on page 16, lines 22 – 23 of the specification. *Slayton* does not teach both imaging and tissue analysis data being returned to the transducer. Applicants respectfully submit that claims 7, 16, and 21, in conjunction with the amendments to independent claims and remarks discussed above, are now in condition for allowance and request that the rejection of the claims be withdrawn.

Applicants have not specifically addressed the rejections of other dependent claims. It is respectfully submitted that, because the dependent claims contain the same limitations as the independent claims discussed above and, along with the remarks, the amendments place all claims in condition for allowance. Applicants respectfully request consideration of the above remarks and withdrawal of all rejections of dependent claims.

CONCLUSION

Claims 1-32 are pending in this application. The Office Action rejections have been traversed, and claims 1, 9, 19, 24, 30, 31, and 32 have been amended to clarify the invention claimed by claims 1, 9, 19, 24, 30, 31, and 21. Claims 1-32 are believed to be in condition for allowance, and Applicants respectfully request that the rejections be withdrawn. The Examiner is invited and encouraged to contact the undersigned attorney of record at (404) 745-2434 if such contact will facilitate a Notice of Allowance for claims 1-32. If any additional fees are due, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855.

Respectfully submitted,

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